REMARKS

In the present Amendment, claim 1 has been amended to recite that the non-polymerizable organoiodine compound, when present, is dissolved in the liquid portion or incorporated into the particles of the particulate polymer portion. By "dissolved in," with regard to the particulate polymer portion, Applicant means that the organoiodine compound is incorporated in the particles of the polymer. This can be achieved, for example, according to Example 10 of the specification. The non-polymerisable organoiodine compounds of the present invention are capable of being dissolved in the monomer from which the particulate polymer portion is made and thus are incorporated throughout the polymer when the monomer polymerises. Therefore, replacing "dissolved in" with "incorporated into the particles" with regard to the particulate portion does not add any new matter as one skilled in the art would understand the two terms to be equivalent in this context.

Claim 5 has been cancelled without prejudice or disclaimer.

New claims 43-54 have been added. Support for claims 43-44 is found, for example, in the paragraph bridging pages 11-12 of the specification. Support for claim 45 is found, for example, at page 6, line 8 of the specification. Support for claims 46-48 is found, for example, at page 9, lines 1-5 and 11-14 and Examples 1 and 2 of the specification. Support for claims 49-51 is found, for example, at page 10, lines 4-10 of the specification. Support for claim 52 is found, for example, at page 11, lines 1-4 of the specification. Support for claims 53-54 is found, for example, at page 14, lines 31-34 of the specification.

No new matter has been added, and entry of the Amendment is respectfully requested.

Upon entry of the Amendment, claims 1, 4, 6-11 and 13-54 will be pending, of which claims 18-41 are withdrawn from consideration.

Response to § 112 Rejection

At page 2 of the Action, claims 1, 4-11, 13-17 and 42 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

The Examiner states that the term "dissolved" in claim 1 seems to imply that the organoiodine compound could only be present in the liquid portion and not the particulate portion; however, the claim states that it may be in either portion so it is vague and indefinite.

As explained above, one skilled in the art would understand that the term "dissolved in" with regard to the particulate polymer portion means that the organoiodine compound is incorporated in the particles of the polymer. Claim 1 has been amended to more clearly indicate that the organoiodine compound is incorporated in the particles of the polymer.

In view of the above, withdrawal of the § 112 rejection is requested.

Response to § 102(b) Rejection

At page 2 of the Action, claims 1, 5, 6, 16 and 17 are rejected under 35 U.S.C. § 102(b) as being anticipated by Lidgren (US 6,586,009).

This rejection should be withdrawn because Lidgren does not disclose the present invention.

Lidgren is cited as teaching a bone cement containing a liquid component containing a polymerizable substance and a powder component containing a plastic substance and an X-ray contrast medium (Abstract), such as iohexol (a non-polymerizable organoiodine compound) (col. 2, lines 65-67).

However, in the method of Lidgren, a water soluble non-ionic X-ray contrast medium is mixed with a plastic substance (col. 2, lines 65-66 and Examples). This portion is combined

with a "liquid component containing a polymerisable substance" to form the bone cement. Any references in Lidgren to the X-ray contrast medium being dissolved are in connection with its behavior in the body in the event that any particles are released from the bone cement after cementation (col. 2, lines 55-57 of Lidgren). As explained below, the contrast agents of Lidgren would not be dissolved in either of the portions, nor in the final bone cement.

The particulate polymer portion

The X-ray contrast medium of Lidgren is merely mixed with "a powder component containing a plastic substance" (col. 2, lines 28-29). This is confirmed by the Examples in which contrast agent in powder form is mixed with the polymer in powder form, i.e., the polymer portion is already in solid particulate form when it is mixed with the contrast agent. The contrast medium of Lidgren thus cannot be dissolved/incorporated in the particulate polymer portion.

The liquid monomer portion

The organoiodine compounds used in Lidgren would not dissolve in the "liquid component containing a polymerisable substance." Lidgren is silent regarding the nature of the liquid phase, therefore it cannot necessarily be considered to be the presently claimed liquid monomer portion. Even if it was, there is no disclosure of the contrast agent being dissolved in the liquid phase. Even if Applicant assumes that the "liquid component containing a polymerisable substance" of Lidgren is a liquid monomer phase according to the present invention, it would have to be a monomer suitable for forming bone cements (claim 1 of Lidgren, "adapted to be mixed for providing a setting mass"), i.e., a hydrophobic acrylic monomer such as methyl methacrylate used in the present invention. Applicants note that the presently claimed organoiodine compounds would have to be hydrophobic in order to dissolve in the monomer or polymer portions (as these bone cement components would be understood to be hydrophobic

themselves). It is therefore implicit from the term "dissolved" in the claims that the organoiodine compounds are hydrophobic. However, the organoiodine compounds used in Lidgren are water soluble (col. 2, lines 28) and are not hydrophobic, and thus would not dissolve in the liquid portion which is hydrophobic. Therefore, Lidgren does not teach or suggest a contrast agent dissolved in a liquid monomer portion, as required by the present claims.

The bone cement

As explained above, the organoiodine compounds of Lidgren do not dissolve in the liquid phase and cannot be incorporated in the particulate phase, as they are merely mixed with the polymer which is already in solid form. When the two phases are mixed to form a bone cement (Applicant notes that there is no actual example of this in Lidgren) the organoiodine compound would not dissolve because it is not soluble in either component.

In view of the above, the present claims are not anticipated by and are novel over Lidgren. Reconsideration and withdrawal of the §102(b) rejection based on Lidgren are respectfully requested.

Response to § 103(a) Rejections

At page 3 of the Action, claims 4, 9-11 and 42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lidgren.

At page 4 of the Action, claims 7 and 8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lidgren in view of Posey-Dowty et al. (US 5,258,420).

At page 4 of the Action, claims 13 and 15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lidgren in view of Wenz (DE 20218668; citations are taken from the English language equivalent US 2005/0287071).

At page 5 of the Action, claim 14 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Lidgren in view of Nies et al. (US 5,650,108).

All the above § 103(a) rejections should be withdrawn because the cited references do not disclose or render obvious the present invention, either alone or in combination.

As discussed above, the difference between the bone cement of Lidgren and the present invention is that the present invention provides a bone cement in which the organoiodine compound is dissolved/incorporated in at least one of the portions. When the monomer and polymer portions are combined to form a bone cement, the organoiodine compound is distributed homogenously throughout the cement. Moreover, as the organoiodine compound is dissolved/incorporated in one of the portions, it does not exist in particulate form.

As disclosed at the end of page 1 of the specification, the existence of insoluble particles of contrast agent in bone cements leads to reduction of strength of the cement. This problem is solved by the present invention which dissolves the contrast agent, thus ensuring that no particles exist to affect the mechanical characteristics of the bone cement. The cement of the present invention has superior strength, even at higher doses of contrast agent than those of Lidgren.

Further, the following advantages of the cements of the present invention are observed:

1. Due to the fact that the organoiodine compound is dissolved in a portion of the cement prior to mixing and setting, the final cement has organoiodine compound distributed homogenously throughout, which is important for monitoring of implants etc.

2. The organoiodine compound is in solution and thus does not consist of particles which can affect the mechanical strength of the cement.

3. The organoiodine compounds are soluble in the cement polymer, but are cleaved due to esterase activity of body fluids to form physiologically tolerable compounds which are soluble in body fluids.

The above advantages can be achieved by using hydrophobic derivatives of organoiodine compounds as disclosed at page 9 of the specification. The chemical nature of the organoiodine compounds of the present invention makes them soluble in either the polymer portion (e.g., Example 31), or in the monomer portion (e.g., Example 34).

Lidgren does not teach or suggest the unexpectedly superior results provided by the present invention. Accordingly, the present claims are not obvious and are patentable over Lidgren.

Posey-Dowty et al is cited as teaching bone cement compositions containing preferably erythromycin and gentamycin as antibiotic agents (col. 3, lines 52-56). Wenz is cited as teaching a bone cement composition that contains, in either the liquid or powder component, a bone morphogenic protein compound ([0029]). Nies et al is cited as teaching a bone cement composition comprising from 2 to 50% by weight of a liquid component (col. 3, lines 30-35). Posey-Dowty et al, Wenz and Nies et al do not make up for the deficiencies of Lidgren.

In view of the above, reconsideration and withdrawal of all the §103(a) rejections are respectfully requested.

New claims 43-54 are patentable over the cited references for at least the same reasons that claims 1, 4, 6-11, 13-17 and 42 are patentable over the cited references, as discussed above.

Allowance is respectfully requested. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

Hui C. Wauters
Registration No. 57,426

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: July 21, 2010

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Torsten ALMEN, et al.

Appln. No.: 10/552,069

Confirmation No.: 6111

Filed: July 14, 2006

For: BONE CEMENT COMPOSITIONS

Docket No: Q90475

Group Art Unit: 1796

Examiner: Angela C SCOTT

EXCESS CLAIM FEE PAYMENT LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

An Amendment Under 37 C.F.R. § 1.111 is attached hereto for concurrent filing in the above-identified application. The resulting excess claim fee has been calculated as shown below **(Small Entity fees apply)**:

	After Amendment		Highest No. Previously Paid For						
All Claims	50	-	42	=	8	X	$26.00	=	$208.00
Independent	11	-	14	=		X	$110.00	=	$.00
					TOTAL			=	**$208.00**

The USPTO is directed and authorized to charge the statutory fee of $208.00 and all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

Hui Chen Wauters

Hui C. Wauters
Registration No. 57,426

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: July 21, 2010